Appeal Brief

By: Philip E. Eggers, et al.

U.S. Serial No. 10/730,633

Filed December 8, 2003

"ELECTROSURGICAL APPARATUS AND SYSTEM WITH IMPROVED TISSUE CAPTURE COMPONENT"

Examiner Jeffrey Gerben Hoekstra

Group Art Unit 3736

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Real Party in Interest

The appealed application is assigned to Neothermia Corporation, now Intact Medical Corporation, a corporation of the State of Delaware, having an office at One Apple Hill, Suite 316, Natick, Massachusetts 01760.

Related Appeals and Interferences

There are no related appeals or interferences known to the Appellants, their legal representatives, or assignee, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

The appealed application was filed December 8, 2003 with claims 1-29.

In an Office action mailed April 24, 2006, the Examiner identified 3 species and required Applicants to elect a single species for prosecution. The Examiner found no claim to be generic.

In a Response to Species Election dated May 19, 2006, Applicants elected with traverse Species I drawn to claims 1-12.

In an Office action mailed June 26, 2006, the Examiner made the species election final and withdrew claims 13-22 from consideration. The Examiner objected to claims 6, 7, and 9. Claim 1 was rejected on the ground of nonstatutory obviousness-type double patenting over claims 18, 26, 30 and 35 of U.S. Patent No. 6,287,304 B1. Claims 1, 3-4, and 12 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 1, 5, 8, 15-17, 20, 22 and 23 of U.S. Patent No. 6,471,659 B1. Claim 1 was rejected on the ground of nonstatutory obviousness-type double patenting over claims 1 and 30 of U.S. Patent No. 6,923,809. Claim 1 was provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1 and 18 of co-pending application, U.S. Serial No. 10/630,336. Claims 1-5, 8, 11 and 12 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Published Application 2002/0072688 A1 by Burbank, et al. (hereinafter, referred to as "Burbank, et al."). Claims 6, 7, 9 and 10 were rejected under 35 U.S.C. § 103(a) over Burbank, et al.

In an Amendment and Response dated August 10, 2006, Applicant amended claim 11 and argued against the claim objections and rejections.

In an Office action mailed October 25, 2006, the Examiner maintained the nonstatutory obviousness-type double patenting rejection against claims 1, 3-4 and 12 over claims 1, 5, 8, 15-17, 20, 22 and 23 of U.S. Patent No. 6,471,659 B1. Additionally with respect to claim 1, the Examiner also maintained the nonstatutory obviousness-type double patenting rejection over claim 1 of U.S. Patent No. 6,923,809 and the provisional nonstatutory obviousness-type double patenting rejection over claim 1 of co-pending application Serial No. 10/630,336. The Examiner also maintained the rejection of claims 1-5, 7, 8, 11 and 12 under 35 U.S.C. § 102(b) as anticipated by Burbank, et al. Claims 6, 7, 9 and 10 also were rejected under 35 U.S.C. 103(a) as being obvious in view of Burbank, et al. All other grounds of rejection were withdrawn. These rejections were made final.

Claims 1-12 have been rejected. Claims 13-29 are withdrawn as being directed to the non-elected species. Applicants filed a Notice of Appeal April 25, 2007, which was received at the Patent Office April 27, 2007. The appealed claims are claims 1-12.

Status of Amendments

No amendments have been filed subsequent to the Office Action mailed October 25, 2006.

Summary of Claimed Subject Matter

Claim 1 is the only independent claim that is the subject of this appeal. Claim 1 generally is directed to electrosurgical apparatus for cutting about and retrieving a tissue volume with an improved capture component. This capture component generally is fashioned with a plurality of thin elongate leafs which extend from a base portion to tip regions having cable guide outlets. A pursing cable assembly configured with a plurality of electrosurgically energizable stainless steel multi-strand braided cables is supported by the multi-leaf structure in a manner wherein the cables are maneuvered through the guide outlets to establish a cutting leading edge which envelopes a target tissue volume as the moving leafs progressively assume the configuration of a tissue capturing cage.

Claim 1 first recites a support member having an internal channel. Such a support member is shown, for example, in Fig. 1 at 32 and described at page 9, lines 17-19. Within the interior channel of the support member is the improved tissue capture component, which is best illustrated in Figs. 9-12 at 340 and described at page 20, line 24 to page 21, line 34. Looking to that portion of the specification and Fig. 10, it may be seen that tissue capture component 340 includes a leaf assembly with a plurality of elongate thin leafs, 300-304, each extending from a base portion 342 to a leaf tip region 344. The embodiment illustrated comprises a leaf assembly with 5 leafs. Each leaf includes a drive component, 350-354, extending along a leaf axis, 356. Each leaf is encased within an electrically insulative flexible leaf cable guide component, 400-404. Fig. 9, shows the leafs of Fig. 10 encased with cable guide components, one of which is illustrated in Fig. 12. As shown in Fig. 12, each of the cable guide components includes a guide channel such as 414 extending to a guide outlet such as 416 in Fig. 16. Cable guide component 400 of Fig. 12 also includes coupling mount 406. Guide channel 414 extends from tip region 344 along the drive component to a guide commencement location 364 (Fig. 10). As described at page 13, lines 5-6 of the specification, the leaf assembly is deployed outwardly from the support member 32. Tissue capture component 340 also includes a pursing cable assembly extending through the cable guide component guide channel 414 and guide outlet 416.

As described at page 22, lines 6-22, the cable assembly employed with capture component 340 is comprised of five cables. These cables extend through support member 32 to enter the guide channel (e.g., 414 in Fig. 12) of a given leaf whereupon it exits from the guide outlet (e.g., 416 in Fig. 16) and is introduced into the guide outlet of a next adjacent leaf, whereupon it extends through the associated channel to a connection located rearwardly of the guide commencement location (e.g., 365 in Fig. 10). Connection is made by fashioning an

enlargement such as a knot or weld ball at the end of the cable. That cable terminus then is inserted through a connector slot (428 in Fig. 15). Looking to Fig. 15, a cable 420 is seen extending into guide channel 408. That cable will exit from guide outlet 416 and reenter the guide outlet of a next adjacent leaf. In this regard, Fig. 15 shows the cable 424 from a next adjacent leaf as having entered guide outlet 416 and extends to an enlargement 426 at its terminus which has been inserted into a keyway shaped slot 428. Each leaf of the capture component 340 is configured in the same manner. Fig. 19 reveals cables 420 and 424 within the channel 414 of guide channel 408.

The pursing cable assembly is electrosurgically energizable and deployable with each leaf tip region 344 to define an electrosurgical cutting arc of initially expanding extent and subsequently pursively contracting extent. Fig. 20 illustrates the tissue capture component 340 in an initial position prior to deployment. In Fig. 21 the orientation of the capture component 340 is illustrated as it extends about one half of the available total axial distance from the instrument forward region 34. Fig. 5 illustrates a fully deployed orientation wherein the leaf tip portions converge at a capture position defining a capture basket configuration or tissue recovery cage substantially encapsulating the entire target tissue volume.

Grounds of Rejection to be Reviewed on Appeal

Whether claims 1-12 are unpatentable under 35 U.S.C. § 102(b) in view of Burbank, et al.

Whether claims 1-12 are unpatentable under 35 U.S.C. § 103(a) in view of Burbank, et al.

Argument

I. Double Patenting

Upon an indication of allowable subject matter, Applicants will submit terminal disclaimers to obviate the double patenting rejections in view of U.S. Patent No. 6,471,659 B1, U.S. Patent No. 6,923,809, and U.S. Patent No. 6,955,653 (previously co-pending Application No. 10/630,336).

II. Claims 1-5, 7, 8, 11, and 12 are patentable and not anticipated by Burbank, et al.

Claim 1

Applicants respectfully submit that Burbank discloses almost none of the recited elements of claim 1. Specifically, claim 1 recites (1) a "tissue capture component...having a leaf assembly comprising a plurality of elongate thin leafs... a said leaf component having a resilient drive component" (2) "an electrically insulative flexible leaf cable guide component" (3) each cable guide component having "one or more guide channels... extending to a guide outlet" and (4) "an integrally formed coupling portion" (5) "a pursing cable assembly extending through a said cable guide component guide channel and said guide outlet, electrosurgically energizable and deployable with each said leaf tip region to define an electrosurgical cutting acr of initially expanding extent and subsequently pursively contracting extent" and (6) "a drive assembly... actuable to move said leaf assembly outwardly from said support member while effecting said deployment of said pursing cable assembly". All of these elements are lacking in Burbank.

In order to circumscribe a volume of tissue, Burbank employs an arch-shaped electrode (20), or plurality of electrodes (20b), that is deployed from a slot extending along a support member. Electrode 20's distal end is anchored to a shaft 18 so that movement of the electrode 20's proximal end causes the electrode to radially expand outwardly from slot 48 to the bowed configuration shown, for example, in Fig. 1. Once deployed, the instrument is rotated to separate the selected sample from surrounding tissue. See paragraphs 0041, 0043, 0044.

Burbank does not disclose a "pursing cable assembly" as recited in the claims. During patent examination, the pending claims must be given their broadest reasonable interpretation, however, that construction must be consistent with the specification. See, Manual of Patent Examining Procedure, § 2111 on claim interpretation. As disclosed in the specification and drawings, the pursing cable assembly of the present invention is configured with a plurality of electrosurgically energizable cables supported by the multi-leaf structure in a manner wherein the cables are maneuvered through the guide outlets to establish a cutting leading edge which envelopes a target tissue volume as the moving leafs progressively assume the configuration of

a tissue capturing cage. Such a pursing cable assembly and its expanding and pursively contracting deployment are illustrated, for example, in Figs. 20 and 21. In those figures, a plurality of cables, 420-424, are seen connected to the tip regions of a leaf assembly including five leafs, 300-304. Fig. 20 shows the leaf assembly in an initial position, while Fig. 21 shows the leaf assembly having been extended to about one half of the available total axial distance from the instrument forward region 34. Fig. 5 shows the instrument in a fully deployed configuration with the pursing cable assembly having been contracted to form a capture basket configuration, or tissue recovery cage, substantially encapsulating the entire target tissue volume.

Burbank's element 16, cited by the Examiner as being a pursing cable assembly, is simply a single wire extending along a conventional trocar tip. Element 16 is energized to advance the trocar tip to a position adjacent or within a given tissue volume. Element 16 is not employed in Burbank's tissue isolation. That function is performed solely by electrode 20 or electrodes 20b. See Paragraphs 0032 and 0038. The cutting element of Burbank also does not deploy outwardly from the support portion forward region as required by claim 1. Burbank's cutting electrode 20, 20b deploys radially outwardly from slot 48 which extends along support member 18. Also, Burbank's cutting element does not define an electrosurgical cutting arc of initially expanding then pursively contracting extent. Once electrode 20, 20b is fully deployed, it is rotated 360° in order to cut about the selected tissue volume. See paragraphs 0041, 0043, 0044. Alternatively, the electrode 20, 20b may be axially moved while rotating the instrument in order to dissect a cylindrical tissue volume. See Figs. 18 and 18 and accompanying specification text.

Burbank also does not disclose the leaf assembly of the present invention which supports the pursing cable assembly. As described above in the Summary section, the leaf assembly comprises a plurality of elongate thin leafs, each extending from a base portion (342) to a leaf tip region (344). Each leaf includes a drive component (350-354) extending along a leaf axis (356). Each leaf also includes an "electrically insulative flexible leaf cable guide component". Utilization of such cable guides into which the leaf components are inserted substantially lessens the complexity of fabrication of the capture component with an attendant improvement in manufacturing costs. One embodiment of a cable guide component is illustrated in Fig. 12 of the application. As that figure shows, a cable guide component 400 includes a "guide channel" 408 and a "coupling portion" 406. A cable guide component surmounts each leaf as shown in Fig. 9, with cables of the pursing cable assembly extending through the appropriate guide channels. See claim 1, lines 12-14.

Element 23 of Burbank has been cited as the flexible leaf cable guide component. As noted in Paragraph 0033 of Burbank, "a layer of insulation 23 is disposed between the return electrode (comprising a major portion of the surface area of the shaft 18) and the portion of the shaft adjacent to the active electrode, which receives the cutting element 20 in its retracted position." See Fig. 3. Thus, element 23 is simply an insulative material coating the inside of the slot from which electrode 20 is deployed. Claim 1 recites "an integrally formed coupling portion mounted with said drive component". It should be noted that each leaf of the leaf assembly includes a drive component, such as those shown at 350-354 of Fig. 10. These should not be confused with the "drive assembly" recited in claim 1 that is actuatable to move the leaf assembly to deploy outwardly from the support member. The "coupling portion" cited as Burbank's element 35 is in fact a "gearing system" contained within the driver portion 24 of Burbank's instrument that rotates shaft 18. See paragraph 0036. As noted above, Burbank does not disclose a pursing cable assembly which is required by claim 1 to extend through the guide channel. Because Burbank does not include a pursing cable assembly, it also should be noted that Burbank lacks the "drive assembly" and "control assembly" recited for effecting deployment and electrosurgical energization of the pursing cable assembly.

Claim 2

Claim 2, dependent on claim 1, additionally recites that the leaf drive component is formed of a resilient metal having "a first width at said base portion extending to at least said guide commencement location" and "said leaf cable guide component is formed of polymeric material."

Looking to Fig. 10, the leaf drive components 350-354 of leafs 300-304 are seen to have base portions 342 extending to a guide commencement location 364. As noted above, the leaf assembly of the present invention is entirely lacking in Burbank, et al. The Examiner erroneously cites the gear mechanism of Burbank as the claimed drive components.

Claim 3

Claim 3, dependent on claim 2, additionally recites that "said leaf cable guide component coupling portion is configured as a sheath surmounting said drive component."

As explained at page 20, lines 21-26 with respect to Figs. 11 and 12, "cable guide 400 is seen to be formed as an elongate polymeric extrusion having a coupling portion 406 and an integrally formed guide channel as at 408. Coupling portion 406 is seen to be formed having a receiving slot 410 which is dimensioned to receive guide support region 370 of leaf 300. Thus

configured, the coupling portion 406 performs in the manner of a sheath surmounting the guide support region 370." Such a sheath is not taught or suggested in Burbank, et al.

Claim 4

Claim 4, dependent on claim 3, recites that the leaf drive component is "configured having a second full width less than said first width extending from said guide commencement location to said tip region" and with the first width defining "oppositely disposed shoulders at said guide commencement location."

This configuration is best illustrated in Fig. 10 wherein one such shoulder is identified at 392. Such a configuration is not disclosed in Burbank, et al.

Claim 5

Claim 5, dependent on claim 3, recites that the leaf drive component is configured having "at least one serrated edge with rearwardly directed points engageable with said sheath".

This configuration also is illustrated in Fig. 10, wherein five leafs are shown having serrated edges as at 376-380. The serrated edges of the guide support regions are configured such that the developed points will engage the internal surface of receiving slot (e.g., 410) under conditions wherein the capture component is drawn from an extended orientation back into the support member (e.g., 32). Such a configuration is nowhere disclosed in Burbank, et al.

Claim 7

Claim 7, dependent on claim 6 recites that "said leaf cable guide coupling portion oppositely disposed rearward end surface has a widthwise extent of about 0.010 inch."

Burbank does not disclose a cable guide with a cable guide coupling portion and therefore cannot disclose the recited widthwise extent.

Claim 8

Claim 8, dependent on claim 2, recites that the leaf cable guide component has one "guide channel configured to surround one or more cables of said pursing cable assembly between said guide outlet and said guide commencement location."

As noted above, Burbank, et al. does not teach or suggest the pursing cable assembly comprising a plurality of cables implemented in the present invention. Burbank, et al. also does not disclose the recited guide component having a guide channel to surround the cables of the pursing cable assembly.

Claim 11

Claim 11, dependent on claim 1, further recites that the leaf cable guide component is "formed of polymeric material" and that each guide channel is "reinforced in the vicinity of said guide outlet to an extent effective to avoid damage occasioned during the deployment of said cable assembly."

Again, Burbank, et al. does not disclose a cable guide component with a guide channel as recited in claim 1. Burbank, et al further does not disclose that the channel is reinforced in the vicinity of the guide outlet. See, guide outlet 416 in Fig. 16.

Claim 12

Claim 12, dependent on claim 11, recited that the leaf drive component is "formed of metal and is configured to define a protective aperture extending across said guide outlet at said tip region."

Again, the Examiner cites the gear mechanism of Burbank, et al as a drive component. As noted previously, the Examiner misunderstands the drive components of the leaf assembly, which are portions of each leaf and not a mechanism for effecting movement. A protective aperture is illustrated, for example at 382 in Fig. 18.

III. Claims 6, 7, 9 and 10 are patentable and unobvious over Burbank, et al.

As described in detail above, Burbank, et al. fails to disclose most of the features of claim 1. No additional references have been cited that disclose, either alone or in combination, the recited features of claim 1 that Burbank, et al. lacks. For that reason alone, claims 6, 7, 9 and 10 should be considered patentable over Burbank, et al. Burbank, et al. also fails to disclose the additional features recited in claims 2-4 from which claims 6, 7 and 9 depend and claim 2 from which 10 depends.

Conclusion

Accordingly, Appellants respectfully urge the Board to overrule the rejection of the appealed claims and to permit the appealed application to pass to issue.

Respectfully submitted,

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Claims Appendix

Claim 1 Apparatus for electrosurgically cutting about a tissue volume, comprising:

a support member having an internal channel and extending to a forward region;

a tissue capture component positioned within said interior channel, having a leaf assembly comprising a plurality of elongate thin leafs extending forwardly from a base portion to a leaf tip region, a said leaf having a resilient drive component extending along a leaf axis from said base portion to a tip region, and an electrically insulative flexible leaf cable guide component having one or more guide channels deposed parallel with said leaf axis and extending to a guide outlet, and an integrally formed coupling portion mounted with said drive component, a said guide channel extending from said tip region along said drive component to a guide commencement location, said leaf assembly being moveable to deploy outwardly from said support member forward region, said capture component having a pursing cable assembly extending through a said cable guide component guide channel and said guide outlet, electrosurgically energizable and deployable with each said leaf tip region to define an electrosurgical cutting arc of initially expanding extent and subsequent pursively contracting extent;

a drive assembly engageable with said leaf assembly base portion and said pursing cable assembly and actuable to move said leaf assembly to deploy outwardly from said support member while effecting said deployment of said pursing cable assembly; and

a control assembly drivably engageable with said drive assembly to effect said actuation thereof and having a terminal electrically coupled with said cable assembly to effect the electrosurgical energization thereof.

Claim 2 The apparatus of claim 1 in which:

said leaf drive component is formed of a resilient metal having a first width at said base portion extending at least to said guide commencement location; and

said leaf cable guide component is formed of polymeric material.

Claim 3 The apparatus of claim 2 in which:

said leaf cable guide component coupling portion is configured as a sheath surmounting said drive component.

Claim 4 The apparatus of claim 3 in which:

said leaf drive component first width is defined between oppositely disposed edges extending from said base portion to said guide commencement location, and is configured having a second full width less than said first width extending from said guide commencement location to said tip region and defining with said first width oppositely disposed shoulders at said guide commencement location; and

said leaf cable guide coupling portion is configured having oppositely disposed rearward end surfaces at said guide commencement location extending in abuttable support before said oppositely disposed shoulders.

Claim 5 The apparatus of claim 3 in which:

said leaf drive component is configured having at least one serrated edge with rearwardly directed points engageable with said sheath configured to engage said leaf cable guide component coupling portion when said leafs are moved rearwardly from a deployed orientation toward said support member.

Claim 6 The apparatus of claim 4 in which:

said leaf drive component first width is about 0.080 inch; and

said leaf drive component second full width is about 0.060 inch.

Claim 7 The apparatus of claim 6 in which:

each said leaf cable guide coupling portion oppositely disposed rearward end surface has a widthwise extent of about 0.010 inch.

Claim 8 The apparatus of claim 2 in which:

said leaf cable guide component has one said guide channel configured to surround one or more cables of said pursing cable assembly between said guide outlet and said guide commencement location.

Claim 9 The apparatus of claim 8 in which:

said guide channel exhibits an internal diametric extent of about 0.015 inch.

Claim 10 The apparatus of claim 2 in which:

said leaf cable guide component polymeric material is polytetrafluoroethylene.

Claim 11 The apparatus of claim 1 in which:

said leaf cable guide component is formed of polymeric material; and

each said guide channel is reinforced in the vicinity of said guide outlet to an extent effective to avoid damage occasioned during the deployment of said cable assembly.

Claim 12 The apparatus of claim 11 in which:

said leaf resilient drive component is formed of metal and is configured to define a protective aperture extending across said guide outlet at said tip region.

Evidence Appendix

None.

Related Proceedings Appendix

None.